

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

CAREFIRST OF MARYLAND, INC.,
GROUP HOSPITALIZATION AND
MEDICAL SERVICES, INC., CAREFIRST
BLUECHOICE, INC., and CFA, LLC d/b/a
CAREFIRST ADMINISTRATORS, on
behalf of themselves and all others similarly
situated,

Plaintiffs,

v.

JOHNSON & JOHNSON and JANSSEN
BIOTECH, INC.,

Defendants.

Case No. 2:23-cv-00629-JKW-LRL

ORAL ARGUMENT REQUESTED

**DEFENDANTS JOHNSON & JOHNSON AND JANSSEN BIOTECH, INC.'S
SUPPLEMENTAL BRIEF IN SUPPORT OF MOTION TO DISMISS**

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Pursuant to the Court’s June 17, 2024 Order, Defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively, “J&J”) respectfully submit this Supplemental Brief in Support of their Motion to Dismiss specifically addressing Plaintiffs’ lack of standing to assert *Walker Process* fraud claims under both federal and state law.

INTRODUCTION

Plaintiffs, as indirect purchasers of Stelara, seek to do something extraordinary in this action: They collaterally attack the enforceability of a J&J patent covering a method of use for ustekinumab (the “’307 Patent”), even though their only connection, at best, to that patent is that they allegedly purchased ustekinumab from someone who purchased ustekinumab from J&J.¹ J&J’s patent has never been enforced against Plaintiffs, and the parties against whom it was enforced chose to settle those disputes rather than pursue the type of challenge Plaintiffs attempt in this case. Those patent settlements are demonstrably procompetitive, in that they allow competitors to enter the market years before the earliest expiration date of the patents owned by J&J. *See* Mot. Dismiss Br., ECF No. 46 at 3; *FTC v. Actavis*, 570 U.S. 136 (2013).

Plaintiffs assert federal and state law claims based on allegations that J&J acquired the ’307 Patent by fraud, a so-called “*Walker Process*” claim. However, numerous federal courts of appeal and district courts have held that indirect purchasers like Plaintiffs lack standing to bring such claims. Departing from this precedent would allow indirect purchasers to resurrect settled patent litigation whenever it was possible to plead inequitable conduct (regardless of whether it can be

¹ On June 27, 2024, J&J received notice of Plaintiff CFA, LLC d/b/a CareFirst Administrators’ (“Carefirst”) voluntary dismissal of all claims against J&J without prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i). ECF No. 91. J&J sent Plaintiffs a letter on June 28, 2024, requesting Plaintiffs respond by Monday, July 1, regarding whether Carefirst’s voluntary dismissal alters Plaintiffs’ state law claims as outlined by “Table 3” of Plaintiffs’ Amended Complaint, ECF No. 36 at ¶ 300 & tbl.3. As of the filing of this brief, Plaintiffs have not provided a substantive response explaining how the voluntary dismissal alters Plaintiffs’ state law claims on a state-by-state basis.

proved by clear and convincing evidence at trial), even if, as here, the settlement allowed for early market entry. Such a result would be particularly inappropriate in this case, where the biosimilar manufacturers who settled with J&J had access to the exact same information as Plaintiffs and made the procompetitive decision to obtain early market entry via a settlement and license.

Nor can Plaintiffs avoid their lack of standing by simply repackaging their antitrust claims as asserting state law consumer protection or unjust enrichment claims. This is because each of the relevant states have either adopted the antitrust standing analysis laid out by the Supreme Court in *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519 (1983) (hereinafter, “AGC”) or an analogous proximate causation requirement.

Finally, to the extent Plaintiffs allege that their state law claims have any independent life beyond their federal claims (they don’t), those claims are preempted by federal law. The Supreme Court of the United States, as well as multiple federal courts of appeals and district courts, have repeatedly held state law claims that are based on alleged fraud on the PTO or on a federal agency generally are preempted.

ARGUMENT

I. Plaintiffs Lack Standing Under Federal Antitrust Law.

The antitrust standing doctrine—which is independent of Article III’s standing analysis—requires courts to determine whether a plaintiff is “a proper party to bring a private antitrust action.” *See AGC*, 459 U.S. 519 at 535 n.3. AGC set forth a five-factor analysis,² but because

² AGC identified five factors to help courts determine whether a potential plaintiff has antitrust standing: “(1) the causal connection between an antitrust violation and harm to the plaintiffs, and whether that harm was intended; (2) whether the harm ‘was of a type that Congress sought to redress in providing a private remedy for violations of the antitrust laws,’; (3) the directness of the alleged injury; (4) ‘the existence of more direct victims’ of the alleged antitrust injury; and (5) ‘problems of identifying damages and apportioning them’ among those directly and indirectly harmed.” *Kloth v. Microsoft Corp.*, 444 F.3d 312, 324 (4th Cir. 2006) (citing AGC, 459 U.S. at 537-45) (internal citations omitted).

several of the factors overlap, many courts use a two-pronged test for assessing antitrust standing: “(1) whether the plaintiff has suffered an antitrust injury; and (2) whether the plaintiff is an ‘efficient enforcer’ of the antitrust laws.” *Supermarket of Marlinton, Inc. v. Valley Rich Dairy*, 161 F.3d 3 n.14 (4th Cir. 1998) (collecting cases) (citing *Todorov v. DCH Healthcare Auth.*, 921 F.2d 1438, 1449 (11th Cir. 1991)); *see Cohen v. Adena Health Sys.*, No. 2:23-CV-02145, 2024 WL 1804990, at *5 (S.D. Ohio Apr. 25, 2024) (noting that courts have “interpreted the[] five [AGC] factors as creating a two-part inquiry . . . a plaintiff must (1) prove an antitrust injury; and (2) demonstrate that they are the proper party to bring the antitrust suit.”).

The Supreme Court explained in *AGC* that “Congress did not intend to allow every person tangentially affected by an [alleged] antitrust violation” to bring antitrust claims. *AGC*, 459 U.S. at 535 (internal citations omitted). Those *directly* harmed by an alleged antitrust violation are the most efficient enforcers of the antitrust laws, and their existence “weigh[s] heavily against” allowing more remote plaintiffs’ antitrust claims to proceed. *Id.* at 545. Further, because more directly injured potential plaintiffs are incentivized to bring meritorious antitrust claims, denying antitrust standing to remote plaintiffs “is not likely to leave a significant antitrust violation undetected or unremedied.” *Id.* at 542 (“The existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement diminishes the justification for allowing a more remote party . . . to perform the office of a private attorney general.”) (footnote omitted).

Moreover, it is well-settled federal antitrust law that there is a fundamental difference between direct and indirect purchasers for standing purposes. In this case, Plaintiffs’ claims relating to the acquisition of the ’307 Patent are based on *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). In *Walker Process*, the Supreme Court held

that a party subject to a patent infringement claim has standing to allege that “enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present.” *Id.* at 174. Plaintiffs claim that, as a result of J&J’s enforcement of the ’307 Patent against others, the biosimilar manufacturers, they suffered damages in the form of alleged delayed competitive entry. In *Illinois Brick Co. v. Illinois*, however, the Supreme Court held that federal antitrust law does not allow indirect purchasers to maintain such claims for damages even while recognizing that direct purchasers may be permitted to do so:

We recognize that direct purchasers sometimes may refrain from bringing a treble-damages suit for fear of disrupting relations with their suppliers. But on balance, and until there are clear directions from Congress to the contrary, we conclude that the legislative purpose in creating a group of “‘private attorneys general’” to enforce the antitrust laws under § 4, . . . is better served by holding direct purchasers to be injured to the full extent of the overcharge paid by them than by attempting to apportion the overcharge among all that may have absorbed a part of it.

431 U.S. 720, 746 (1977) (internal citation and footnote omitted).

Although *Illinois Brick Co.* does not *per se* preclude indirect purchasers from seeking equitable relief, the policy it articulates and distinction between purchasers it reflects go directly to why, under the AGC factors, indirect purchasers do not have standing for *Walker Process* claims. The Second Circuit’s treatment of purchaser standing in *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 691–92 (2d Cir. 2009) is on point and expressly noted the Supreme Court’s concern with expanding the scope of parties with antitrust standing to assert *Walker Process* claims:

To be sure, the *Walker Process* Court also noted that allowing antitrust recovery “accord[ed]” with the “long-recognized procedures” that controlled how parties could challenge a patent’s validity, 382 U.S. at 176-77 . . . thereby suggesting that the Court may not have envisioned expanding the universe of potential patent challengers.

Id. at 691. As a result, the Second Circuit took care to clarify that its ruling was extremely narrow, extending standing only to direct purchasers in situations where—unlike the patent at issue in this action—the patent was already held unenforceable for inequitable conduct:

On the other hand, we do not pass lightly over the defendants’ objections to expanding the universe of patent challengers. The risk of disturbing the incentives for innovation dictates that we tread carefully. As a result, we decline to decide whether purchaser plaintiffs *per se* have standing to raise *Walker Process* claims. In this case, the plaintiffs are challenging an already tarnished patent. We are able to grant them antitrust standing without altering the typical limits on who can start a challenge to a patent’s validity. We therefore hold only that purchaser plaintiffs have standing to raise *Walker Process* claims for patents that are already unenforceable due to inequitable conduct.

Id. at 691-692. Indeed, federal courts have deemed direct purchasers the “‘preferred’ antitrust plaintiffs.” *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 508 (Fed. Cir. 2012) (“[D]irect purchasers are not only eligible to sue under the antitrust laws, but have been characterized as ‘preferred’ antitrust plaintiffs[.]”). And as *In re DDAVP* shows, even when analyzing claims brought by such “preferred” plaintiffs, courts have expressed reluctance about expanding the scope of parties that can maintain a *Walker Process* challenge.

Here, as indirect purchasers, Plaintiffs are not the right parties to bring *Walker Process* fraud claims under federal law. Their relationship to the acquisition and enforcement of the ’307 Patent is simply too attenuated and their injury too remote compared to more direct “victims” of the challenged conduct. Indeed, the most direct theoretical “victims” of the challenged conduct—the biosimilar manufacturers—chose to settle any challenges to the ’307 Patent rather than pursue those challenges. The biosimilar manufacturers are the parties best positioned to balance the risk and benefit of pursuing such a challenge and with the most incentive to do so if it made sense. The biosimilar manufacturers’ decisions not to do so reflects judgments that settling was the best route to early market entry, *i.e.*, was procompetitive. The indirect purchaser Plaintiffs should not be

permitted to second-guess those judgments, resurrect challenges laid to rest by the biosimilar manufacturers, and attempt to overturn the effect of the procompetitive settlement agreements.³

Multiple courts applying *AGC* have held that indirect purchasers like Plaintiffs here lack standing to bring such claims. In *Farag*, for example, the court held that “too many of [the *AGC*] factors [were] left wanting” in part because the indirect purchasers’ purported injury was “down the distribution chain” and “purely incidental.” *Farag v. Health Care Serv. Corp.*, No. 17 C 2547, 2017 WL 2868999, at *6 (N.D. Ill. July 5, 2017) (“*Walker Process* does not confer standing on a party whose only connection to the patentee is as an indirect purchaser of products covered by the patent.”). Similarly, in *K-Dur*, the court emphasized that the indirect purchasers were “‘remote part[ies]’ whose interest in ‘antitrust enforcement’ [was] diminished” because, as here, drug manufacturers allegedly blocked by the fraudulently obtained patent chose to settle their claims rather than pursue claims or defenses based on the alleged fraud. *In re K-Dur Antitrust Litig.*, No. 01-1652, 2007 WL 5297755, at *18 (D.N.J. Mar. 1, 2007). The court explained that it would “turn antitrust policy on its head” to “allow parties having the most tenuous relationship with a particular patent holder’s . . . attempt to enforce a fraudulently procured patent against its competitors to assert claims that parties who may have suffered more direct injury have settled, or simply chosen not to pursue.” *Id.* After surveying the case law, the *K-Dur* court found that indirect purchasers did not have antitrust standing to pursue *Walker Process* claims:

. . . the majority of decisions which have considered the issue, have reached the conclusion that, unlike competitors, *customers* (e.g., indirect purchasers) do not, generally speaking, suffer exposure to the type of harm that *Walker Process* claims

³ For the same reasons, Plaintiffs’ lack standing to challenge conduct relating to the acquisition of the patents from Momenta. *See Am. Compl.* ¶¶ 153-70. As indirect purchasers, Plaintiffs are also not the proper parties to challenge the alleged anticompetitive nature of the Momenta patent acquisition. As with Plaintiffs’ ’307 Patent *Walker Process* claims, Plaintiffs attempt to second-guess decisions made by parties who were more directly affected by the alleged conduct. *See AGC*, 459 U.S. at 545.

are specifically designed to remedy.

Id. at *17; *see also In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 831 n.11 (N.D. Ill. 2020) (“[T]he complaint does not assert a *Walker Process* claim, . . . likely because these plaintiffs would lack standing to do so.”) (internal citation omitted), *aff’d sub nom. Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709 (7th Cir. 2022).⁴

The Court should reach the same result here. Like *Farag*, indirect purchasers of ustekinumab are too remote to appropriately bring *Walker Process* claims. And just like in *K-Dur*, J&J’s potential competitors decided to settle their patent litigation—using the type of procompetitive, early-entry-date-settlements the Supreme Court endorsed in *Actavis*, 570 U.S. at 152—rather than pursuing the fraud claims Plaintiffs allege here. The Court should reject indirect purchasers’ attempt to “open the door to additional rounds of litigation on matters that have conclusively and *lawfully* been resolved,” “inject a significant level of uncertainty into the process of adjudicating patent disputes,” and “extend antitrust standing to an extraordinary level.” *K-Dur*, 2007 WL 5297755 at *18.

⁴ These decisions are in accord with courts’ general—and appropriate—reluctance to extend standing to indirect purchasers. *Monsanto Co. v. McFarling*, No. 4:00CV84, 2002 WL 32069634, at *3 (E.D. Mo. Nov. 5, 2002) (finding counterclaim plaintiff “lack[ed] standing to bring antitrust claims under any of the statutes he has cited. He is an indirect purchaser, and he does not have standing to bring such a claim.”), *aff’d*, 363 F.3d 1336 (Fed. Cir. 2004); *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187 (S.D.N.Y. 2019) (dismissing antitrust claim based on patent misuse as to indirect purchasers who “d[id] not allege that Keurig directly overcharged them, but rather that one or more intermediaries passed on overcharges” because “[t]he Supreme Court clearly admonished the use of pass-on theories to establish standing in treble damages actions” based on a concern that “is no less present in the context of an action for an injunction.”); *In re Circular Thermostat*, No. MDL C05-01673WHA, 2005 WL 2043022, at *8 (N.D. Cal. Aug. 24, 2005) (holding “that, as indirect purchasers, plaintiffs have no standing to sue for violations of federal antitrust laws” in antitrust action premised on trademark misuse and/or fraud before the PTO in procuring a trademark) (internal citations omitted).

Notably, the Fourth Circuit has never extended antitrust standing under *Walker Process* to an indirect purchaser. This makes sense given the fundamental remoteness of such claims brought by strangers to a patent. Long-standing Fourth Circuit case law is instructive. For example, in *Kloth v. Microsoft Corp.*, 444 F.3d 312 (4th Cir. 2006), end purchasers of computers loaded with Microsoft software attempted to bring antitrust claims against Microsoft. The Fourth Circuit noted that the only plead concrete “injuries amount to a form of overcharge passed on to the plaintiffs by OEMs and retailers.” *Id.* at 323. Such injuries are the same as those alleged by Plaintiffs here. The Fourth Circuit held that under *AGC*, the indirect purchasers did not have antitrust standing. *Id.* at 324-325. *Pocahontas Supreme Coal Co., Inc. v. Bethlehem Steel Corp.*, 828 F.2d 211 (4th Cir. 1987) is similarly instructive. Plaintiff Pocahontas sold mining land to Coal America in exchange for a royalty. Defendant National Mines terminated its contract with Coal America. Pocahontas sought treble damages and injunctive relief under the antitrust laws against National Mines. The Fourth Circuit held that Pocahontas had no standing: “[w]e agree with the district court that the chain of causation between the claimed antitrust violation and this claimed injury to Pocahontas is too attenuated to be considered proximate, hence to support standing to invoke the private injunctive relief sought.” *Id.* at 220; *see also Laurel Sand & Gravel, Inc. v. CSX Transp., Inc.*, 924 F.2d 539, 543-44 (4th Cir. 1991) (finding shipper was an indirect purchaser without “standing” to sue national railroad for its refusal to sell trackage rights to shortline railroad which sought to carry shipper’s product).

II. Plaintiffs Lack Standing Under State Antitrust Law.

Plaintiffs also lack standing to bring *Walker Process* antitrust claims under state law for the reasons set forth above. The state antitrust claims in the Amended Complaint can be grouped into four categories: (1) states where the highest appellate court has explicitly adopted *AGC*; (2) states where lower state courts have applied *AGC*; (3) states where federal courts have predicted

that state courts would apply *AGC*; and (4) one state, Minnesota, that has rejected *AGC* (but applies similar factors). For the first three categories, Plaintiffs do not have antitrust standing for the same reasons discussed above. And Plaintiffs have failed to meet the standard articulated by Minnesota as well.

A. States Where the Highest Appellate Court Has Explicitly Adopted *AGC* (Connecticut, Iowa, Nevada, and Nebraska).

The highest courts in Connecticut, Iowa, Nevada, and Nebraska have all applied *AGC*.⁵

See Tremont Pub. Advisors, LLC v. Conn. Res. Recovery Auth., 333 Conn. 672, 692 (Conn. 2019) (Connecticut law “is consistent with the requirements under federal antitrust law that the plaintiff must have suffered an ‘antitrust injury’ and that the plaintiff must be an ‘efficient enforcer’ of the antitrust laws.”);⁶ *Southard v. Visa U.S.A. Inc.*, 734 N.W.2d 192, 198 (Iowa 2007) (“[W]e apply the *AGC* factors to determine whether the plaintiffs may recover under Iowa law.”); *Nev. Recycling & Salvage, Ltd. v. Reno Disposal Co., Inc.*, 423 P.3d 605, 607-08 (Nev. 2018) (applying *AGC*); *Kanne v. Visa U.S.A. Inc.*, 723 N.W.2d 293, 299 (Neb. 2006) (“We conclude that appellants lack standing under *Associated General Contractors* to seek recovery for Visa and MasterCard’s alleged violation of [Nebraska’s antitrust act].”).⁷ Accordingly, *AGC* should be applied to Plaintiffs’ antitrust claims under the laws of these states, and because Plaintiffs fail to satisfy that test, their *Walker Process* claims under Connecticut, Iowa, Nevada, and Nebraska antitrust law

⁵ *See* Exs. A, B.

⁶ *See also Brown v. Hartford Healthcare Corp.*, No. X03-CV-22-6152239-S, 2023 WL 7150051, at *7 (Conn. Sup. Ct. Oct. 26, 2023) (applying *AGC*); *see Conn. Gen. Stat. § 35-44b* (“[T]he courts of this state shall be guided by interpretations given by the federal courts to federal antitrust statutes.”).

⁷ These decisions are consistent with the harmonization provisions in Iowa, Nevada, and Nebraska antitrust law. *See* Iowa Code Ann. § 553.2; Nev. Rev. Stat. Ann. § 598A.050; Neb. Rev. Stat. § 59-829.

must be dismissed for the same reasons as the federal claims as described above. *See e.g., In re Dynamic Random Access Memory (Dram) Antitrust Litig.*, 516 F. Supp. 2d 1072 (N.D. Cal. 2007) (same); *In re Cattle & Beef Antitrust Litig.*, 687 F. Supp. 3d 828, 841, n.5 (D. Minn. 2023) (same); *Nevada Recycling & Salvage, Ltd. v. Reno Disposal Co., Inc.*, 423 P.3d 605 (Nev. 2018) (same); *In re Dealer Mgmt. Sys. Antitrust Litig.*, 362 F. Supp. 3d 510, 541–545 (N.D. Ill. 2019) (same).

B. States Where State Trial and Intermediate Courts Have Adopted AGC (Arizona, California, District of Columbia, Kansas, Maine, Michigan, New Mexico, New York, North Carolina, North Dakota, South Dakota, Vermont, and Wisconsin).

The highest appellate courts in Arizona, California, District of Columbia, Kansas, Maine, Michigan, New Mexico, New York, North Carolina, North Dakota, South Dakota, Vermont, and Wisconsin have yet to rule on this issue, but various trial and appellate courts have held that AGC governs the application of their antitrust laws.⁸ In addition, all of these states include harmonization provisions instructing courts to construe their state antitrust laws in harmony with federal law.⁹ When interpreting state antitrust law, the majority of federal courts view the

⁸ See Exs. A, B; *Luscher v. Bayer A G*, No. CV 2004-014835, 2005 WL 6959406 (Ariz. Sup. Sep. 16, 2005) (Arizona); *Wholesale Electricity Antitrust Cases I & II*, 55 Cal. Rptr. 3d 253, 265 (Cal. Ct. App. 2007) (California); *Vinci v. Waste Mgmt., Inc.*, 43 Cal. Rptr. 2d 337, 339 (Cal. Ct. App. 1995) (California); *Peterson v. Visa U.S.A., Inc.*, 2005 WL 1403761, at *5 (D.C. Sup. Ct. Apr. 22, 2005) (District of Columbia); *Wrobel v. Avery Dennison Corp.*, No. 05CV1296, 2006 WL 7130617, at *2 (Kan. Dist. Ct. Feb. 01, 2006) (Kansas); *Knowles v. Visa U.S.A., Inc.*, 2004 WL 2475284, *5 (Me. Sup. Ct. 2004) (Maine); *Stark v. Visa U.S.A. Inc.*, 2004 WL 1879003, at *4 (Mich. Cir. Ct. July 23, 2004) (Michigan); *Nass-Romero v. Visa U.S.A. Inc.*, 279 P.3d 772, 776 (N.M. Ct. App. 2012) (New Mexico); *Ho v. Visa U.S.A., Inc.*, No. 112316/00, 2004 WL 1118534, at *2 (N.Y. Sup. Ct. 2004), *aff'd*, 793 N.Y.S.2d 8 (N.Y. App. Div. 2005) (New York); *Crouch v. Crompton Corp.*, 2004 WL 2414027, *18 (N.C. Sup. Ct. 2004) (North Carolina); *Cornelison v. Visa U.S.A., Inc.*, No. CIV 03-1350 (S.D. Cir. Ct. Sep. 28, 2004) (South Dakota, as discussed in hearing transcript attached as Ex. C) (South Dakota); *Beckler v. Visa U.S.A., Inc.*, 2004 WL 2115144, *2–3 (N.D. Dist. 2004) (North Dakota); *Fucile v. Visa U.S.A., Inc.*, No. S1560-03 CNC, 2004 WL 3030037, at *3 (Vt. Sup. Dec. 27, 2004) (Vermont); *Strang v. Visa*, 2005 WL 1403769, *3 (Wis. Cir. Ct. 2005) (Wisconsin).

⁹ See Mot. Dismiss Br., ECF No. 46 at 26, n.15.

existence of harmonization provisions as sufficient to allow the court to apply *AGC* to claims brought under state antitrust laws. *See In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig.*, No. 9 CV 3690, 2015 WL 3988488, at *4 (N.D. Ill. June 29, 2015) (“The Court is persuaded that the presence of a statutory harmonization provision (either statutory or common law), absent any countervailing statutory law or case law from a state appellate court, is sufficient to permit a district court to apply federal antitrust-standing law—including *AGC*—to claims brought under that state’s antitrust laws.”); *In re Dynamic Random Access Memory (Dram)*, 516 F. Supp. 2d at 1095 (same); *In re Dealer Mgmt. Sys.*, 362 F. Supp. 3d at 545 (same).

Accordingly, given the willingness of lower state courts to apply *AGC* and the lack of any binding countervailing authority, numerous district courts have regularly concluded that the highest court from these states will also apply *AGC*. *See, e.g., In re Cattle & Beef Antitrust Litig.*, 687 F. Supp. 3d at 841 n.5; *In re Dealer Mgmt. Sys.*, 362 F. Supp. 3d at 541-45; *In re Dairy Farmers*, 2015 WL 3988488 at *7; *In re Dynamic Random Access Memory (Dram)*, 516 F. Supp. 2d at 1095; *In re Refrigerant Compressors Antitrust Litig.*, No. 2:09-MD-02042, 2013 WL 1431756, at *10-11 (E.D. Mich. Apr. 9, 2013); *Sahagian v. Genera Corp.*, No. CV 08-7613-GW PJWX, 2009 WL 9504039, at *6 (C.D. Cal. July 6, 2009); *Beckler v. Visa U.S.A., Inc.*, No. 09-04-0030, 2004 WL 2475100, at *4 (N.D. Dist. Sept. 21, 2004).

The same result should apply in this case and this Court should dismiss Plaintiff’s *Walker Process* claims under Arizona, California, District of Columbia, Kansas, Maine, Michigan, New Mexico, New York, North Carolina, North Dakota, South Dakota, Vermont, and Wisconsin state antitrust laws for lack of standing.

C. States Where Federal Courts Have Predicted That State Courts Would Adopt AGC (Alabama, Hawaii, Illinois, Maryland, Mississippi, New Hampshire, Oregon, Puerto Rico, Rhode Island, Tennessee, Utah, and West Virginia).

State courts in Alabama, Hawaii, Illinois, Maryland, Mississippi, New Hampshire, Oregon, Puerto Rico, Rhode Island, Tennessee, Utah, and West Virginia have not explicitly addressed whether AGC should apply for antitrust standing. However, none of these states have rejected the application of AGC, and all have harmonization provisions either in statutory or common law.¹⁰ Given the lack of countervailing authority rejecting the use of AGC, other federal courts have routinely concluded that the highest court in these states will likely apply AGC.¹¹ *See e.g., In re Interior Molded Doors Antitrust Litig.*, No. 3:18-CV-00718-JAG, 2019 WL 4478734, at *16 (E.D. Va. Sept. 18, 2019); *In re Cattle & Beef Antitrust Litig.*, 687 F. Supp. 3d at 841, n.5; *In re Dealer Mgmt. Sys.*, 362 F. Supp. 3d at 541-45; *In re Dynamic Random Access Memory (Dram)*, 516 F. Supp. 2d at 1095; *In re Refrigerant Compressors Antitrust Litig.*, No. 2:09-MD-02042, 2013 WL 1431756, at *10-11 (E.D. Mich. Apr. 9, 2013); *Sahagian*, 2009 WL 9504039 at *6; *United States ex rel. Blaum v. Triad Isotopes, Inc.*, 104 F. Supp. 3d 901, 930 (N.D. Ill. 2015) (Illinois); *Or. Laborers-Empl’rs Health & Welfare Tr. Fund v. Philip Morris, Inc.*, 17 F. Supp. 2d 1170 (D. Or. 1998) (Oregon); *havePOWER, LLC v. Gen. Elec. Co.*, 183 F. Supp. 2d 779 (D. Md. 2002) (Maryland); *Seafarers Welfare Plan v. Philip Morris*, 27 F. Supp. 2d 623 (D. Md. 1998) (Maryland).

Thus, the Court should apply AGC and dismiss Plaintiffs’ *Walker Process* claims under

¹⁰ See Exs. A, B; *see also* Mot. Dismiss Br., ECF No. 46 at 26 n.15 (listing harmonization provisions); *Vandenbergh v. Aramark Educ. Servs., Inc.*, 81 So. 3d 326, 333 (Ala. 2011) (“It is well settled that ‘[t]he federal law relating to monopolization governs Alabama antitrust actions.’”) (internal citation omitted); *Davis v. Four Seasons Hotel Ltd.*, 228 P.3d 303, 310 (Haw. 2010) (analyzing federal antitrust standing law when applying HRS § 480–13); *Cnty. of Cook v. Phillip Morris, Inc.*, 817 N.E.2d 1039, 1045–46 (Ill. App. Ct. 2004); *State v. Jonathan Logan, Inc.*, 301

Alabama, Hawaii, Illinois, Maryland, Mississippi, New Hampshire, Oregon, Puerto Rico, Rhode Island, Tennessee, Utah, and West Virginia state antitrust laws for lack of standing.

D. Minnesota Has Not Adopted AGC, But the Outcome Should Be the Same.

The Minnesota Supreme Court has declined to adopt AGC. *See Lorix v. Crompton Corp.*, 736 N.W.2d 619, 632 (Minn. 2007) (“The AGC factors . . . do not provide the benchmark for standing under Minnesota antitrust law.”). Despite its refusal to adopt AGC, the *Lorix* court still acknowledged that some of the AGC factors overlap with Minnesota’s antitrust-standing inquiry. Specifically, *Lorix* notes that “[s]tanding under Minnesota antitrust law must be defined by some prudential limits informed by foreseeability, proximate cause, remoteness, and relation of the injury to the purposes of the antitrust law.” *Id.* at 631. “[O]therwise, almost any antitrust violation would provide almost any citizen with a cause of action arising from the resulting ripples of harm throughout the state’s economy.” *Id.*; compare AGC, 459 U.S. at 542 (factors three and four, “the directness of the alleged injury” and “the existence of more direct victims”).

Md. 63, 67-68 (Md. App. Ct. 1984); *In re Mid-Atlantic Toyota Antitrust Litig.*, 541 F. Supp. 62, 64 (D. Md. 1981); *Harrah’s Vicksburg Corp. v. Pennebaker*, 812 So.2d 163 (Miss. 2002); *The Shell Co. (Puerto Rico), Ltd. v. Los Frailes Service Station, Inc.*, 551 F. Supp. 2d 127, 135 (D.P.R. 2007) (“[T]he Puerto Rico courts generally follow federal antitrust law when interpreting local antitrust laws.”); *ERI Max Enter’r, Inc. v. Streisand*, 690 A.3d 1351, 1335 n.1 (R.I. 1997) (“[T]he Rhode Island Antitrust Act must be construed in harmony with judicial interpretations of comparable federal antitrust statutes insofar as practical, except where provisions of this chapter are expressly contrary to applicable federal provisions as construed.”); *State ex rel Leech v. Levi Strauss & Co.*, No. 79-722-III, 1980 WL 4696, at *2 n.2 (Tenn. Ch. Ct. 1980) (“Authorities which define the character of private damage suits under the federal anti-trust statutes . . . are most persuasive.”); *Tenn. Med. Ass’n v. BlueCross BlueShield of Tenn., Inc.*, 229 S.W.3d 304 (Tenn. Ct. App. 2007) (citing to AGC); *Aikens v. Debow*, 541 S.E.2d 576, 582 (W. Va. 2000) (citing AGC principles in a tort case).

¹¹ In the absence of a clear rule provided by state law, federal courts analyzing “unsettled areas of state law” must “carefully predict how the state’s highest court would resolve the uncertainties.” *Salveson v. JP Morgan Chase & Co.*, 166 F. Supp. 3d 242, 256–57 (E.D.N.Y. 2016) (internal citation omitted). “In predicting how a state’s highest court would resolve the issue, courts must ‘give the fullest weight to pronouncements of the state’s highest court . . . while giving proper regard to relevant rulings of the state’s lower courts.’” *Id.* (internal citation omitted).

Here, Plaintiffs fail to meet the standard set forth in *Lorix*. Specifically, Plaintiffs are indirect purchasers who are too far removed from the alleged antitrust injury to establish proximate cause. Their injuries are speculative and incidental to the harm allegedly suffered by direct purchasers or potential competitors to J&J, who are better positioned to bring such claims. *See supra* Section I. Indeed, another district court analyzing *Lorix* similarly concluded that “[i]ndirect [p]laintiffs’ injuries are too remote and speculative to afford standing under Minnesota antitrust law.” *In re Dairy Farmers*, 2015 WL 3988488 at *12 (noting that “despite the *Lorix* court’s refusal to adopt *AGC*, the Court is nonetheless persuaded by . . . its concession that any assessment of antitrust standing must be ‘informed by foreseeability, proximate cause, remoteness, and relation of the injury to the purposes of the antitrust law.’”). Thus, Plaintiffs lack standing to assert a claim under Minnesota’s antitrust statute. *See also Contant v. Bank of Am. Corp.*, No. 17 CIV. 3139 (LGS), 2018 WL 1353290, at *7-8 (S.D.N.Y. Mar. 15, 2018) (finding “[p]roximate cause is required to bring an antitrust action under Minnesota, Arizona and North Carolina law. Although the Court has declined to apply the *AGC* analysis to antitrust claims under Minnesota law, Minnesota imposes at least a proximate cause requirement for bringing an antitrust claim,” and “[f]or the same reasons that the Complaint fails to satisfy the *AGC* efficient enforcer factors, it also fails to allege proximate cause. All of Plaintiffs’ claims are dismissed for failure to allege facts plausibly showing proximate cause.”); *In re Cattle & Beef Antitrust Litig.*, 687 F. Supp. 3d at 841 (“The Court will also dismiss the antitrust claim arising under Minnesota law because, though Minnesota does not apply *AGC* explicitly, it similarly considers proximate causation and directness, which Plaintiffs failed to establish.”).

III. Plaintiffs' Other State Law Claims Improperly Repackage Their Antitrust Claims.

Plaintiffs' lack of antitrust standing is also fatal to their other state law claims, which simply repackage their federal and state antitrust claims.¹² Numerous courts have explained that "the directness inquiry in antitrust-standing law is predicated on the well-known concept of proximate causation," which is necessary in state law consumer protection and unjust enrichment claims. *In re Dairy Farmers*, 2015 WL 3988488 at *16; *see Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302, 315 n.23 (4th Cir. 2007) ("The Supreme Court has likened the common-law tort concept of proximate cause to the directness inquiry required by the additional AGC factors . . .").

Therefore, just as the remoteness of Plaintiffs' injury and the presence of better-suited potential plaintiffs bars Plaintiffs' antitrust claims here, it also bars their non-antitrust state law claims. *See Dairy Farmers*, 2015 WL 3988488 at *16 (dismissing claims on antitrust standing grounds, then dismissing consumer protection claims and unjust enrichment claims for the same reasons); *Supreme Auto Transp. LLC v. Arcelor Mittal*, 238 F. Supp. 3d 1032, 1041 (N.D. Ill. 2017), *aff'd sub nom. Supreme Auto Transp., LLC v. Arcelor Mittal USA, Inc.*, 902 F.3d 735 (7th Cir. 2018) (dismissing consumer protection claims and unjust enrichment claims because the

¹² Separately, Plaintiffs have tried to improperly transform claims under Florida consumer protection law into standalone antitrust claims. *See Am. Compl.* ¶¶ 355(f); 373(kk) (listing Florida's consumer protection statute as the basis for state law monopolization and attempted monopolization claims). Florida has an antitrust law, *see Fla. Stat. Ann. § 542.15*, but Florida courts have held that *Illinois Brick* bars indirect purchasers like Plaintiffs from recovering under it. *See Mack v. Bristol-Myers Squibb Co.*, 673 So.2d 100, 107-08 (Fla. Dist. Ct. App. 1996). Federal courts have rejected indirect purchasers' similar attempts to "repackage their dead-on-arrival antitrust claims as FDUTPA claims" because doing so would "render[] moot" the "contours of Florida's antitrust laws." *In re Dairy Farmers*, 2015 WL 3988488 at *19. And even if Plaintiffs were allowed to plead an antitrust claim under the FDUTPA, Plaintiffs have not alleged proximate causation, a necessary element of an FDUTPA claim, for all of the same reasons they do not have antitrust standing, *see Dairy Farmers*, 2015 WL 3988488, at *19; *2P Com. Agency S.R.O. v. SRT USA, Inc.*, No. 2:11-CV-652-FTM-29, 2013 WL 246650, at *4 (M.D. Fla. Jan. 23, 2013) ("[C]ausation must be direct, rather than remote or speculative."); *In re Cattle & Beef Antitrust Litig.*, 687 F. Supp. 3d at 841 (same).

“reasons behind plaintiffs’ failure to meet the AGC factors equally apply to a proximate cause analysis” applicable to those claims); *MSP Recovery Claims, Series LLC v. Mallinckrodt ARD Inc.*, No. 3:20 C 50056, 2020 WL 1330373, at *5 (N.D. Ill. Mar. 23, 2020) (holding that plaintiffs do not have antitrust standing under AGC and dismissing their consumer protection claims, which “implicate Plaintiffs’ antitrust standing” through their proximate causation requirements) (internal citation omitted); *In re Aluminum Warehousing Antitrust Litig.*, No. 13-MD-2481 KBF, 2014 WL 4277510, at *38 (S.D.N.Y. Aug. 29, 2014) (dismissing indirect purchasers’ claims on antitrust standing grounds and also dismissing state law claims on proximate cause grounds); *R.J. Reynolds Tobacco Co. v. Philip Morris Inc.*, 199 F.Supp.2d 362, 396 (M.D.N.C. 2002) (dismissing state antitrust and common law claims because “[p]laintiffs do not allege any facts that suggest that [d]efendant’s conduct is unlawful beyond the conduct that is the basis for their failed federal [antitrust] claims.”), *aff’d sub nom. RJ Reynolds Tobacco Co. v. Philip Morris USA, Inc.*, 67 F. App’x 810 (4th Cir. 2003); *Formula One Licensing, B.V. v. Purple Interactive Ltd.*, 2001 WL 34792530, at *4 (N.D. Cal. Feb. 6, 2001) (“Where a plaintiff fails to state an antitrust claim, and where an unfair competition claim is based upon the same allegations, such state claims are properly dismissed.”).

IV. Plaintiffs’ State Law Claims Are Preempted by Federal Law.

Finally, even if Plaintiffs have standing, it is well-settled that state law claims based on allegations of fraud on the PTO are preempted by federal patent law and should be dismissed on that independent basis. *K-Dur*, 2007 WL 5297755, at *23 (“Plaintiffs’ *Walker Process* and ‘sham litigation’ claims are subject to dismissal because they are preempted by federal patent law”); *see also Farag*, 2017 WL 2868999 at *3 (“Because there is simply no theory for proving a *Walker Process* antitrust violation in this case that would not require a showing of misconduct before the PTO, federal patent law preempts any state antitrust cause of action premised on [such] conduct

before the PTO.”) (internal quotations omitted); *cf. Daiichi Sankyo, Inc. v. Apotex, Inc.*, No. CIVA.030937(SDW-MCA), 2009 WL 1437815, at *9 (D.N.J. May 19, 2009) (“State law tort claims are preempted by federal law if they are based on nothing more than misconduct before the PTO.”).

Plaintiffs’ claims are also subject to preemption under *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001) because they are based on fraud on a federal agency. *Buckman* involved alleged fraud on the FDA in the application for approval of a medical device. The Supreme Court found implied preemption:

Given this analytical framework, we hold that the plaintiffs’ state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Id. at 348 (internal footnotes omitted).¹³

The same result applies here. Plaintiffs’ claims related to the acquisition of the ’307 Patent are based on allegations related to J&J’s conduct before a federal agency, the PTO, and therefore implicate the same concerns reflected in *Buckman*. Indeed, courts have recognized this and held that claims, like Plaintiffs’ claims here, that are based on alleged misconduct before the PTO are preempted under *Buckman*. *LCS Group, LLC v. Shire LLC*, C.A. 18-cv-2688 (AT), 2019 WL 1234848, *6-13 (S.D.N.Y. March 8, 2019) (relying on *Buckman* and holding “to allow [plaintiff] to bring fraud claims based on alleged misconduct before the PTO, . . . would be ‘contrary to

¹³ See also *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1327 (Fed. Cir. 2017) (relying on *Buckman* to hold that the BPCIA, which as here allowed the manufacturers who settled with J&J to rely on J&J’s FDA dossier for ustekinumab and thus created the potential for generic biologic entry, is not a field in which state antitrust has historically acted and therefore finding no presumption against preemption).

Congress' preemptive regulation in the area of patent law,'” and so “LCS’s fraud claims based on the IPR petition are, therefore, preempted by federal patent law.”) (internal citations and quotations omitted); *Lockwood v. Sheppard, Mullin, Richter & Hampton, LLP*, C.A. 09-cv5157-JFW, 2009 WL 9419499, *5-11 (C.D. Cal. Nov. 24, 2009) (same). This result is also consistent with *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, in which the court likewise held that *Walker Process* claims styled as state antitrust claims “not only [arose] out of patent law, but rest[ed] entirely on patent law” and as such “federal patent law preempts any state antitrust cause of action premised on Bayer’s alleged bad faith conduct before the PTO.” 363 F. Supp. 2d 514, 544 (E.D.N.Y. 2005). The Second Circuit affirmed *sub nom* that there was preemption. *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), as corrected (June 17, 2010):

Because the Walker Process claims are preempted by patent law, see Cipro III, 363 F.Supp.2d at 543-44, we transferred the indirect purchaser plaintiffs’ appeal to the Federal Circuit, while retaining jurisdiction over the direct purchaser plaintiffs’ appeals.

Id. at 103, n.10 (emphasis added).

The Federal Circuit did not reach the issue of preemption in its decision in *In re Ciprofloxacin*, 544 F.3d 1323, 1333 (Fed. Cir. 2008), but it has previously addressed preemption on similar facts to the case at bar in *Semiconductor Energy Lab’y Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1381 (Fed. Cir. 2000), *amended* (Apr. 5, 2000). In *Semiconductor Energy*, Samsung, which was subject to an allegation of patent infringement on a patent a federal judge found unenforceable for inequitable conduct, brought a New Jersey RICO claim based on the same conduct. *See id.* Samsung emphasized that the “misconduct is not a ‘garden-variety’ instance of inequitable conduct[.]” *Id.* The Federal Circuit held federal patent policy preempted the claim: “We agree with SEL that the federal patent laws preempt Samsung’s New Jersey RICO counterclaims.” *Id.* at 1382. The same holds in the case at bar. Plaintiffs allege that the state law

claims are triggered because J&J obtained and asserted the '307 Patent—the exact same steps that trigger an inequitable conduct claim in a federal court. Plaintiffs use lots of words in their Amended Complaint, but all those words are simply euphemisms for holding a patent and enforcing it, because the only acts alleged to maintain an alleged monopoly in this case are the enforcement of patents.¹⁴ To be clear, J&J is not claiming that patent law preempts all state law claims. Simply the claims as plead by Defendants.

Lower courts analyzing state law claims premised on *Walker Process* have found such claims subject to federal preemption. *K-Dur* is on point. That court, in reliance on *Semiconductor Energy*, considered state law monopolization claims premised on *Walker Process*, and found that the “the wrong[s] alleged and for which state [law] . . . damages [are] sought [are] no more than bad faith misconduct before the PTO,” and “on th[at] basis alone, the *Walker Process* . . . claims . . . [were] preempted by federal law.” *K-Dur*, 2007 WL 5297755 at *23-24. *See also Farag*, 2017 WL 2868999 at *3 (“To the extent Plaintiffs might be seeking relief under the Illinois Antitrust Act, 740 Ill. Comp. Stat. 10/3, it is preempted inasmuch as it relates to the *Walker Process* claim. Because there is simply no theory for proving a *Walker Process* antitrust violation in this case that would not require a showing of misconduct before the PTO, federal patent law preempts any state antitrust cause of action premised on [such] conduct before the PTO.”) (internal quotations and citation omitted); *cf. Daiichi Sankyo*, 2009 WL 1437815 at *9 (“State law tort claims are preempted by federal law if they are based on nothing more than misconduct before the PTO.”).

CONCLUSION

For the foregoing reasons, J&J respectfully requests that the Court dismiss Plaintiffs’

¹⁴ The decision in *Semiconductor Energy Lab'y Co.* is particularly notable because it found preemption even before the Supreme Court’s definitive discussion of fraud on the agency state law claim preemption a year later in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Amended Complaint with prejudice.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2024, I caused to be served a copy of the foregoing Memorandum in Support of Defendants' Supplemental Brief in Support of Motion to Dismiss on all counsel of record via the Court's CM/ECF system.

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